12/16/54

PTO/SB/21 (03-03)

ø,, •		Approved for use through 04/30/2003. OMB 0651-0031 at and Trademark Office; U.S. DEPARTMENT OF COMMERCE
TRANSMITTAL	Application Number	on of information unless it displays a valid OMB control number. 10/711707
IKANSIMITIAL	Filing Date	9/30/2004
FORM	First Named Inventor	Spray et al
(to be used for all correspondence efter initial	(ing) Art Unit	3736
	Examiner Name	not yet assigned
Total Number of Pages in This Submission	Attorney Docket Number	B0368-US01
	ENCLOSURES (Check all tha	it apply)
Fee Transmittal Form Fee Attached  Amendment/Reply After Final Affidavits/declaration(s) Extension of Time Request Express Abandonment Request Information Disclosure Statement Certified Copy of Priority Document(s) Response to Missing Parts/ Incomplete Application Response to Missing Parts under 37 CFR 1.52 or 1.53	Drawing(s)  Licensing-related Papers  Petition  Petition to Convert to a Provisional Application  Charge of Correspondence Addr  Terminal Disclaimer  Request for Refund  CD, Number of CD(s)  Remarks  This transmittal form  Information Disclosures Statement  rorm PTO 1449  ritemational Search Report for PCT USO:	Other Enclosure(s) (please identify below):
	URE OF APPLICANT, ATTORN	EY, OR AGENT
Firm John R. Merkling or Individual Signature Date /5 Decc	MA Joos	
C	RTIFICATE OF TRANSMISSIO	N/MAILING
I hereby certify that this correspondence is being fi first class mail in an envelope addressed to: Comm	ssimile transmitted to the USPTO or deposited visioner for Patents, Washington, DC 20231 on	with the United <u>States Postal Service with suffi</u> cient postage as this date: 12.15.04
Typed or printed Gina K, Aga		

This collection of information is required by 37 CPR 15. The information is required to Allahar or retain a benefit by the public which is to file (and by the USPR) crosses) an application. Confidentiality is governed by 37 LPR 15. This information is required to Complete, including gathering, personal control of the Part of the

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

lication No. 10/711707 nation Disclosure Statement ket No.: B0368-US01

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

pplication of:

Spray et al 10/711707 Examiner: not yet assigned

erial No.:

Art Unit: 3736

Filed:

9/30/2004

For: Biologic Fluid Sampling Apparatus

Customer Number:

24994

Commissioner of Patents Post Office Box 1450 Alexandria, Virginia 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir.

Pursuant to 37 C.F.R. §1.56, Applicant brings to the attention of the Examiner the document-listed on the attached PTO Form 1449; copies of the non-US references and publications are enclosed. A copy of the International Search Report for corresponding PCT Application PCT US03/13877 is enclosed.

It is believed this Information Disclosure Statement is being filed before the first Office Action on the merits.

This submission does not represent that a search has been made or that no better information exists and does not constitute an admission that the listed document alone or in combination with other documents. is considered to be material to patentability as defined under 37 C.F.R. § 1.56(b).

It is believed no fee is required in connection with the filing of this statement. If this is incorrect, please charge any such fee to deposit account 03-2316.

15 December 2001

Respectfull submittee

John Merkling; Reg. No.

Gambro, Inc.

10810 W. Collins Ave. Lakewood, CO 80215 (303) 231-4270



Sheet Lof 5

FORM PTO-1449 C.S. DEPARTMENT OF COMMERCE (Modified) PATEN CHURCHE DEMARK OFFICE	ATTY. DOCKET NO. B0368-US01	SERIAL NO. 10/711707
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	APPLICANT Spray et al	
(Use several sheets if necessary)	FILING DATE 9/30/2004	GROUP 3736

		U.S. I	PATENT DOCUMENTS			
EXAMINER INITIAL	PATENT NUMBER	ISSUE DATE	PATENTEE	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	6,540,696	4/1/03	Dillon et al			
	5,752,936	5/19/98	Chen			
	5,259,392	11/9/93	Schmitt			
	4,932,418	6/12/90	Coburn			
	6,540,696	4/1/03	Dillon et al			
	6,626,884	9/30/03	Dillon et al			
	4,784,650	11/15/88	Coburn			
	5,030,209	7/9/91	Wanderer et al			
	5,112,311	5/12/92	Utterberg et al			
	5,782,820	7/21/98	Roland			
	6,235,006	5/22/01	Dillon et al			
	6,165,157	12/26/00	Dillon et al			
	5,827,239	10/27/98	Dillon et al			
	2001/0006610	7/5/01	Miller et al			
	6,692,479	2/17/04	Kraus et al			
	2002/0143244	10/3/02	Kensey et al			
	4,152,213	5/1/79	Ahnell			
	4,820,297	4/11/89	Kaufman et al			
	4,900,321	2/13/90	Kaufman et al			
	4,945,060	7/31/90	Turner et al			
	5,094,955	3/10/92	Calandra et al			
EXAMINER				DATE CO	ONSIDERED	

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through

Sheet 2 of 5

FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE (Modified) PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. B0368-US01	SERIAL NO. 10/711707
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	APPLICANT Spray et al	
(Use several sheets if necessary)	FILING DATE 9/30/2004	GROUP 3736

		U.S. I	PATENT DOCUMENTS			
EXAMINER INITIAL	PATENT NUMBER	ISSUE DATE	PATENTEE	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	5,162,229	11/10/92	Thorpe et al			
	5,164,796	11/17/92	Di Guiseppi et al			
	5,217,876	6/8/93	Turner et al			
	5,293,210	3/8/94	Berndt			
	5,314,855	5/24/94	Thorpe et al			
	5,518,895	5/21/96	Thorpe et al			
	5,567,598	10/22/96	Stitt et al			
	5,676,644	10/14/97	Toavs et al			
	5,702,383	12/30/97	Giesler et al			
	5,716,798	2/10/98	Monthony et al			
	5,795,773	8/18/98	Read et al			
	5,811,061	9/22/98	Martinson et al			
	5,856,175	1/5/99	Thorpe et al			
	5,858,769	1/12/99	DiGuiseppi et al			
	5,912,115	6/15/99	Hyman et al			
	5,952,218	9/14/99	Lee et al			
	5,976,827	11/2/99	Jeffrey et al			
	5,427,920	6/27/95	Berndt et al			
	6,152,901	11/28/00	Arruego et al			
	6,153,400	11/28/00	Matsumura et al			
	6,197,577	3/6/01	Jeffrey et al			
EXAMINER				DATE CO	NSIDERED	

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through

Sheet 3 of 5

		Sheet 3 of 3
FORM PTO-1449 U.S. DEPARTMENT OF COMMER (Modified) PATENT AND TRADEMARK OFFICE	CE ATTY. DOCKET NO. B0368-US01	SERIAL NO. 10/711707
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	APPLICANT Spray et al	
(Use several sheets if necessary)	FILING DATE 9/30/2004	GROUP 3736

		U.S.	PATENT DOCUMENTS			
EXAMINER INITIAL	PATENT NUMBER	ISSUE DATE	PATENTEE	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	6,251,624	6/26/01	Matsumura et al			
	6,267,242	7/31/01	Nagata et al			
	6,520,948	2/18/03	Mathias et al			
	D 323,033	7/21/92	DiGuiseppi			

FOREIGN P	ATENT OR PUB	LISHED FOREIGN P.	ATENT APPLIC	ATION	
DOCUMENT NUMBER	PUBLISHED DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION
WO03/078964	9/25/03	PCT			
EP0,627,893	2/13/02	EP			
EP1,064,959	1/3/01	EP			
EP1,156,325	11/21/01	EP			
JP08320317	12/3/96	JP Abstract			
WO00/07642	2/17/00	PCT			
WO01/06258	1/25/01	PCT			
WO01/32828	5/10/01	PCT			
WO02/11855	2/14/02	PCT			
WO98/28057	7/2/98	PCT			
WO99/58094	11/18/99	PCT			

EXAMINER	DATE CONSIDERED

Sheet 4 of 5

FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE (Modified) PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. B0368-US01	SERIAL NO. 10/711707
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	APPLICANT Spray et al	
(Use several sheets if necessary)	FILING DATE 9/30/2004	GROUP 3736

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)
International Search Report for corresponding application PCT/US03/13877
Photograph "Gambro BCT Sample Bag System"
"SampLok Sampling Kit (SSK) Platelet transfer kit" brochure
Photograph "CharterMed Syringe System (10 ml)" and instructions 2 pages.
Photograph "CharterMed Bag System" and instructions 2 pages.
Photograph "MacoPharma Bag System"
Photograph "Gambro BCT Sample Bulb System"
"BacT/Alert 3D: We asked our customers how we could make MacT/Alert 3D any easier", Organon Teknika, 2000.
Claeys et al, "Bacterial Screening of Platelet Concentrates", Quality Assurance Department, Dienst voor het bloed, Rode kruis-Vlaanderen, Brussels, Belgium
Cummings et al, "Validation Trial for Microbiology Pre-transfusion Testing of Platelets", Australian Red Cross Blood Service Bass, 10/31/00, pp. 1-6.
De Korte et al, "Reduction of the degree of bacterial contamination for whole blood collections, *Transfusion*, 1999;39, supplement, S73.
Janz et al, "A Comparison of Two Methods for the Detection of Bacteria in Red Cell Concentrates", Waikato Blood Transfusion Services, Hamilton, New Zealand.
Laan et al, "Improved safety and extended shelf-life of leuco-depleted platelet concentrates by automated bacterial screening, Foundation Sanquin bloodsupply, Bloodbank Noord-Holland, Alkmaar. 3 pages.
Laport et al, "Detection of Bacterial Contamination of Platelet Concentrates", Blood Bank Geldersche Rivieren, Nijmegen, The Netherlands.
Liu et al, "Reduction of Platelet Transfusion-Associated Sepsis by Short-Term Bacterial Culture", Vox Sang, 1999:77:1-5.

Sheet 5 of 5

FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE (Modified) PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. B0368-US01	NO. B0368-US01 SERIAL NO. 10/711707	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	APPLICANT Spray et al		
(Use several sheets if necessary)	FILING DATE 9/30/2004	GROUP 3736	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)				
	Ollgaard et al, "Monitoring of Bacterial Growth in Platelet Concentrations", Department of Clinical Immunologi, Odense, University Hospital, Denmark.			
	Schelstraete et al, "1122: Evaluation of the BacT/Alert for the Detection of Bacterial Grown in Platelet Concentrates Prepared with PAS II", Red Cross Blood Center, Department of Microbiology, KU Leuven, Belgium.			
	Schelstraete et al, "Evaluation of the BacT/Alert for the Detection of Bacterial Grown in Platelet Concentrates Prepared with PAS II", Red Cross Blood Center, Department of Microbiology, KU Leuven, Belgium.			
	Schelstraete et al, "Prevalence of bacteria in leuco-depleted pooled platelet concentrates and apheresis platelets", Blood Transfusion Center, Leuven, Belgium, 3 pages.			
	Vuk et al, "Bacterial Contamination of Blood Products", Croatian Institute of Transfusion Medicine, Zagreb, Croatia.			
	Wendel et al, "Screening of Bacterial Contamination in a Routine Scale for Blood Components Production in a Brazilian Blood Bank", Blood Bank-Hospital sirio-Libanes, Brazil.			
	Wendel et al, "Screening of Bacterial Contamination in a Routine Scale for Blood Components Production in a Brazilian Blood Bank", Associac o Brasileira de Bancos de Sanque-ABBS, Sao Paulo-Brazil.			

EXAMINER	/Renee Danega/	DATE CONSIDERED	09/09/2009